2026590105

p. 1

RECEIVED CENTRAL FAX CENTER JUN 2 6 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of	:)
ROSENBERG et al.)
PCT/EP2003/011205)
Serial No. 10/530,483)
Filing or 371(c) Date: April 6, 2005)

For: METHOD FOR PRODUCING SOLID GALENIC FORMULATIONS USING A CROSSLINKED NON-THERMOPLASTIC CARRIER

I hereby certify that this correspondence is either being deposited with the United Stres Postal Service with sufficient postage as first class mail in an envelope addressed to Commissioner for Fatents, P.O. Box 1450, Alexandria, Virginia 22313-1450, or being facsimile transmitted to the United State: Patent and Trademark Office, Fax No. 703-872-9306, on June 26, 2005.

Typed or printed name of person signing fuis certificate: Jason D. Voight

Signature: V

Honorable Commissioner for Patents Alexandria, Virginia 22313-1450

SUBMISSION OF ENGLISH TRANSLATION OF IPER

Please enter the enclosed English Translation of the Internation : | Preliminary

Examination Report in the above-reference application.

Please charge any shortage in fees due in connection with the fling of this paper to

Deposit Account No. 14.1437. Please credit any excess fees to such account.

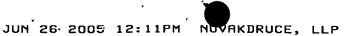
Respectfully submitted,

NOVAK DRUCE DeLUCA & QUIGG LLP

Jason D. Voight

Reg. No. 42,205

Customer No. 26474 1300 Eye Street, N.W. Suite 400 East Washington, D.C. 20005 (202) 659-0100





Translation

PATENT COOPERATION TREATY

PCT/EP2003/011205

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

A11	(1 01 12 acie 50 and Rule 70)
Applicant's or agent's file reference M742135-PCT	FOR FURTHER ACTION See Notificat on of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP2003/011205	International filing date (day/month/year) Priority date (day/month/year) 09 October 2003 (09.10.2003)
International Patent Classification (IPC) or na A61K 9/16	ational classification and IPC
Applicant	ABBOTT GMBH & CO. KG
This international preliminary examinant and is transmitted to the applicant account.	
	5 sheets, including this cover sheet.
This report is also accompanied amended and are the basis for the 70.16 and Section 607 of the Ac	by ANNEXES, i.e., sheets of the description, c. sims and/or drawings which have been this report and/or sheets containing rectifications made before this Authority (see Rule diministrative Instructions under the PCT).
These annexes consist of a total	
3. This report contains indications relating	to the following items:
I Basis of the report	
II Priority	
III Non-establishment of o	ninion with account a
' IV Lack of unity of inventi	pinion with regard to novelty, inventive step and andustrial applicability
	for Article 35(2) with regard to novelty, inventiv: step or industrial applicability; as supporting such statement
VI Certain documents cited	
VII Certain defects in the int	ernational application
	the international application
	· ·
ate of submission of the demand	Date of completion of this report
27 April 2004 (27.04.2004)	
me and mailing address of the IPEA/EP	Authorized officer
esimile No.	Telephone No.
- DOTONE A MAGE A	

Form PCT/IPEA/409 (cover sheet) (July 1998)



KDRUCE,	LLP	202659010

The Province in the American Control of the Control	I remational application No.
INTERNATIONAL PRELIMINARY EXAMINATION REPORT	PCT/EP2003/011205
L Basis of the report	
1. With regard to the elements of the international application:*	-
the international application as originally filed	
the description:	·
pages 1-13	, as originally file
pages	, filed with the deman
pages, filed with the lette	rcf
the claims:	
pages1-9	, as originally filed
pages, as amended (to	og I fer with any statement under Article I
pages	, filed with the demand
pages, filed with the ketter	ro'
the drawings:	
pages	, as originally file
	, filed with the demand
pages, filed with the letter	ro:
the sequence listing part of the description;	
pages	, as originally file
pages, filed with the letter	, flied with the demand
the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international prelim or 55.3).	nin vy examination (under Rule 55,2 and
With regard to any nucleotide and/or amino acid sequence disclosed in the in preliminary examination was carried out on the basis of the sequence listing:	ter actional application, the international
contained in the international application in written form.	•
filed together with the international application in computer readable form.	
furnished subsequently to this Authority in written form.	
furnished subsequently to this Authority in computer readable form.	
The statement that the subsequently furnished written sequence listing does international application as filed has been furnished.	
The statement that the information recorded in computer readable form is iden been furnished.	tic to the written sequence listing has
The amendments have resulted in the cancellation of:	
the description, pages	
the claims, Nos.	
the drawings, sheets/fig	•
This report has been established as if (some of) the amendments had not been made beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).*	e, : i ace they have been considered to go
Replacament sheets which have been furnished to the receiving Office in response to an in n this report as "originally filed" and are not annexed to this report since they do and 70.17).	
Any replacement sheet containing such amendments must be referred to under tiem I and a	
m PCT/IPEA/409 (Box I) (July 1998)	

PAGE 3/6 * RCVD AT 6/26/2005 1:07:10 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/0 * DNIS:8729306 * CSID:2026590105 * DURATION (mm-ss):02-42

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

nternational application No. PCT/EP 03/11205

V.	V. Reasoned statement under Article 35(2) with regard to sovelty, invencitations and explanations supporting such statement		ovelty, inventive step of	ndustrial app	olicability;	
1.	Statement			•		
	Novelty (N)	Claims	1	9	YES	
!		Claims			NO .	
	Inventive step (IS)	Claims	1	9	YES	
		Claims			NO	
	Industrial applicability (IA)	Claims	1	- 9	YES	
		Claims		· 	125 NO	

Citations and explanations

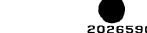
The documents are numbered in the same sequence in which they appear in the search report.

D1 describes a method of producing stable granules. At 30°C, 13.2 % omeprazole, 66.6 % crosslinke; polyvinylpyrrolidone (Kollidon @ CL-M), 6.6 % polyalkoxylated glycerides (Gelucire ®) and 13.2 % Akomed P R are mixed and allowed to cool (see example 6). In corparison with the differently composed formulations of examples 1 to 5, the formulation of example 6 displays far quicker release of the active substance (see table 8).

D2 discloses a process for producing a stable and rapidrelease formulation, wherein the components are mixed at 150°C and then cooled immediately. The mixt re contains 32.6 % itraconazole, 48.9 % hydroxypropylmethylcellulose (HPMC), 13 % Na-croscamellose and 5.5 % gly:erol monostearate (see example 6).

In D3 the components of a mixture (inter alia 66 % carbochromene-HCl, 7.4 % wax and 2.9 % sodium carboxymethyl cellulose) are mixed at 70°C or 90°C, cooled and compressed with further adjuvants to form tablets (see

Form PCT/IPEA/409 (Box V) (January 1994)



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

atemational application No. ECT/EP 03/11205

examples 3 and 5).

In D4 a mixture of 20 % active substance, 20 % crospovidone and 40 % HPMC is melted at 1:5°C, cooled to room temperature and further processed to produce forms of medicaments, such as tablets (see example 10 and paragraph [0036]).

- 1. Novelty
 - The subject matter of claims 1 to 9 appears to be novel within the meaning of PCT Article 33(2) in light of the available documents.
- 2. Inventive step The subject matter of claims 1 to 9 involves an inventive step within the meaning of PCT Article 33(3).

The problem addressed by the present invention is the devising of alternative processes for producing a dosage form which rapidly releases poorly soluble active substances.

The proposed solution to the problem as a process which involves mixing 50 to 99.4 % of a crosslinked, non-thermoplastic excipient, [.5 to 30 % of a thermoplastic adjuvant and 0.1 to 4:.5 % of an active substance at temperatures of a: least 70°C and then cooling.

D2 represents the closest prior art. It describes a process for producing a stable, rapid-selease formulation in which the components are mixed at 150°C and then cooled immediately. The mixture

Form PCT/IPEA/409 (Box V) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

i iternational application No.
PCT/EP 03/11205

contains 32.6 % itraconazole (active substance),
48.9 % hydroxypropylmethylcellulose (HPMC; thermoplastic polymer), 13 % sodium croscarmellose (crosslinked, non-thermoplastic excipient) and 5.5
glycerolmonostearate (see example 6).

D1 discloses the production of stable granules having the composition claimed in chaim 1 of the present application (see example 6). The method steps involve the mixing of the components at 60°C or 30°C and then cooling the compounts.

Since example 6 of D1 displays considerably faster release of the active substance than the other formulations in that document (see table 8), a person skilled in the art would be prompted to select this composition for producin; a rapid-release dosage form. However, he would have no reason to carry out the production pacess at higher temperatures, as with the D2 to D4 pacesses.

Therefore the subject matter of claim: 1 to 9 involves an inventive step.

3. Industrial applicability The subject matter of claims 1 to 9 his industrial applicability within the meaning of PIT Article 33(4).

Form PCT/IPEA/409 (Box V) (January 1994)